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PPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/621,698	07/17/2003		Ronald Charles Bernotas	AM100986	1509
25291	7590	11/10/2004		• EXAMINER	
WYETH			CHANG, CELIA C		
PATENT LA		JP		ADT LDUT	0.000.000.000
5 GIRALDA	FARMS		ART UNIT	PAPER NUMBER	
MADISON,	NJ 0794	0	1625		

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/621,698	BERNOTAS ET AL.				
Office Action Summary	Examiner	Art Unit				
	Celia Chang	1625				
The MAILING DATE of this communication app						
Period for Reply		•				
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a repl If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	I36(a). In no event, however, may a reply by within the statutory minimum of thirty (30 will apply and will expire SIX (6) MONTHS a, cause the application to become ABAND	be timely filed  b) days will be considered timely. from the mailing date of this communication.  SONED (35 U.S.C. § 133).				
Status	·					
1) Responsive to communication(s) filed on <u>08/1</u>	<u>9/04</u> .	,				
This action is <b>FINAL</b> . 2b)⊠ This action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
4) Claim(s) <u>1-8 and 15-20</u> is/are pending in the a	polication.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) <u>1-8 and 15-20</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	or election requirement.	•				
Application Papers		<b>S</b>				
9) The specification is objected to by the Examine	er.	·				
10)☐ The drawing(s) filed on is/are: a)☐ acc	epted or b) objected to by t	he Examiner.				
Applicant may not request that any objection to the						
Replacement drawing sheet(s) including the correc						
11) The oath or declaration is objected to by the Ex	kaminer. Note the attached Of	flice Action or form PTO-152.				
Priority under 35 U.S.C. § 119		*				
12) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 11	9(a)-(d) or (f).				
a) All b) Some * c) None of:						
1. Certified copies of the priority document	•					
2. Certified copies of the priority document						
3. Copies of the certified copies of the prio	·	eived in this National Stage				
application from the International Burea * See the attached detailed Office action for a list	, , , ,	reived				
See the attached detailed Office action for a list	of the certified copies flot rec	eiveu.				
	,					
Attachment(s)						
1) Notice of References Cited (PTO-892)		mary (PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Ma	ail Date mal Patent Application (PTO-152)				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	6) Other: .	na. i atom rpphoator (i 10-132)				

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## **DETAILED ACTION**

1. Applicant's election without traverse of Group II, claims 1-8, 15-20 reading on W is CR<sub>2</sub> in the reply filed on Aug. 19, 2004 is acknowledged.

Claims 9-14 have been canceled. Claims 1-8, 15-20 are pending.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernotas et al. US 6,727,246.

# Determination of the scope and content of the prior art (MPEP §2141.01)

Bernotas et al. '246 disclosed indolylpiperidinyl/pyrrolidinyl compounds having identical 5HT6 receptor activity as the instant claims, see claim 9, col. 34, lines 3-4, 24, 32-33.

#### Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between Bernotas et al. '246 and the instant claims is that instead of the various position of the heterocyclic ring being linked to the 1-indolyl moiety, the Bernotas et al. '246 has 1-heterocyclic ring linkage only. It is noted that when R5 is hydrogen, the heterocyclic moiety is fully saturated with all the positions analogous with each other.

## Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the Bernotas et al. '246 reference and the explicit exemplification of the species as claimed in claim 9 would find the instant claims prima facie obvious **because** the instant claims are mere position isomers of the prior art examples which have *identical* utility as the instant. Position isomerism has long been recognized in the pharmaceutical art to be structural prima facie. Ex parte Engelhard 208 USPQ 343, In re Mehta 146 USPQ 284. The same process of the prior art (see claim 20, '246) upon

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employing the prima facie obvious position isomeric starting material and modification using conventional N-protecting skill of the chemical art, would give the instantly claimed products.

3. Claims 1-8, 15-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 15-19 of U.S. Patent No. 6,727,246. Although the conflicting claims are not identical, they are not patentably distinct from each other for the same reason as delineated supra.

Determination of the scope and content of the prior art (MPEP §2141.01)

Bernotas et al. '246 claimed position isomers of the instant claims, see claim 9, col. 34, lines 3-4, 24, 32-33, which have identical 5HT6 receptor activity as the instant claims.

Ascertainment of the difference between the prior art and the claims (MPEP §2141,02)

The difference between Bernotas et al. '246 and the instant claims is that instead of the various position of the heterocyclic ring being linked to the 1-indolyl moiety, the Bernotas et al. '246 has 1-heterocyclic ring linkage only. It is noted that when R5 is hydrogen, the heterocyclic moiety is fully saturated with all the positions analogous with each other.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the Bernotas et al. '246 reference and the explicit exemplification of the species as claimed in claim 9 would find the instant claims prima facie obvious **because** the instant claims are mere position isomers of the prior art examples which have *identical* utility as the instant. Position isomerism has long been recognized in the pharmaceutical art to be structural prima facie. Ex parte Engelhardt 208 USPQ 343, In re Mehta 146 USPQ 284. The same process of the prior art (see claim 20, '246) upon employing the prima facie obvious position isomeric starting material and modification using conventional N-protecting skill of the chemical art, would give the instantly claimed products.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang Nov. 8, 2004

Celia Chang Primary Examiner Art Unit 1625